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IN THE

Supreme Court of the United States

UNIVERSITY OF ROCHESTER,

Petitioner,

v.

G.D. SEARLE & CO., INC.; MONSANTO COMPANY; PHARMACIA CORPORATION; and PFIZER INC.,

Respondents.

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF AMICI CURIAE THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, THE UNIVERSITY OF TEXAS SYSTEM, CARNEGIE MELLON UNIVERSITY, CASE WESTERN RESERVE UNIVERSITY, CORNELL UNIVERSITY, WISCONSIN ALUMNI RESEARCH FOUNDATION, THE RESEARCH FOUNDATION FOR SUNY, THE UNIVERSITY OF MARYLAND, EMORY UNIVERSITY, THE UNIVERSITY OF FLORIDA, THE JOHNS HOPKINS UNIVERSITY IN SUPPORT OF THE PETITION

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THE INTEREST OF THE AMICI CURIAE[1]

The *Amici Curiae* are a group of eleven public and private universities and private educational research corporations whose research scientists conduct fundamental and ground-breaking research. The *Amici* are: The Regents of the University of California, three campuses of the University of Texas System (The University of Texas M.D. Anderson Cancer Center, The University of Texas Southwestern Medical Center at Dallas, The University of Texas Medical Branch at Galveston) Carnegie Mellon University, Case Western Reserve University, Cornell University, Emory University, the University of Florida, The Johns Hopkins University[2], The Research Foundation for the State University of New York, the Wisconsin Alumni Research Foundation (WARF), and the Attorney General of the State of Maryland on behalf of the State and the University of Maryland, Baltimore.

The *Amici* have a substantial interest in the Petition for a Writ of Certiorari filed by the University of Rochester. The *Amici* write specifically to emphasize the detrimental impact of the Federal Circuit's recent written description

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1. No counsel for any party authored this brief either in whole or in part, and no persons other than the *Amici Curiae* and their counsel made any monetary contribution to its preparation or submission. The parties' written consents to the filing of this brief have been filed with the Clerk of the Court.

2. The Johns Hopkins University joins as an *Amicus* for the limited purpose of requesting resolution of the issue of whether there is a separate written description requirement. The University does not join a position on whether a separate written description requirement is required by the statute but does believe that all statutory requirements were met by the Rochester patent.

precedent[3] on the ability of research institutions to protect their inventions and to transfer this technology to the private sector for further development and commercialization. The application of the heightened written description requirement to inventions created by research institutions is of immense concern to the *Amici* and has far-reaching implications for the patentability of ground-breaking research conducted at universities. Under this new written description doctrine, if the inventor has not actually reduced to practice and provided a detailed description of the structure of the claimed invention, the claims may be invalidated for insufficient written description. This Court's decision whether to consider this issue will have a significant impact on the continuing viability of technology transfer programs at universities and on the equitable allocation of intellectual property rights between universities and the private sector.

SUMMARY OF ARGUMENT

This case provides the Court with an opportunity to bring clarity and certainty to the nature and scope of the disclosure requirement embodied in 35 U.S.C. § 112, Paragraph 1 ("§ 112, P. 1"). The *Amici* seek the Court's attention on this issue for three reasons. First, this case squarely presents the issue of statutory interpretation of the disclosure provision of § 112, P. 1. Second, this case crystallizes the intense intra-circuit conflict on the proper interpretation of the written description requirement, which the Federal Circuit repeatedly has refused to resolve by *en banc* review. Third, and foremost to the *Amici*, this case disrupts the settled expectations of the inventing community, particularly of universities engaged in basic research. The fate of pioneering inventions based on such fundamental research depends on the correct statutory

3. The Federal Circuit's recent written description precedent includes *Regents of the University of California v. Eli Lilly, Inc.*, *Enzo Biochem, Inc. v. Gen-Probe Inc.*, and most recently, *University of Rochester v. G.D. Searle.*

interpretation of § 112, P. 1. If the statutory interpretation set forth in *University of Rochester v. G.D. Searle*, 358 F.3d 916, 921, *reh'g denied*, 375 F.3d 1303 (Fed. Cir. 2004) prevails, these inventions will be exceedingly difficult to patent and previously issued patents on such important inventions may be invalidated.

At issue in this case is the statutory construction of § 112, P. 1, one of the most important statutes in patent law. Because the statute embodies the *quid pro quo* of the constitutional patent bargain, the statute must be interpreted in a manner such that the patent bargain is properly effectuated. The plain language of the statute mandates one disclosure provision that requires a written description of the invention in such "full, clear, concise, and exact terms" to enable the skilled artisan to make and use the claimed invention. Furthermore, when the statute is viewed in its proper historical and legal context, this interpretation of the statute is confirmed. Neither the express statutory language nor a contextual analysis supports the separate, free-standing written description requirement set forth by the Federal Circuit in *Rochester*.

The new statutory interpretation of § 112, P. 1 fundamentally changes patent law in a manner that disrupts the expectations of the inventing community. By instituting a rule under which inventions must be described in a precise structural way, it creates a higher bar to patentability and a powerful weapon to invalidate already issued patents. Such a rigid rule conflicts with the goals of providing a uniform body of patent law and encouraging innovation. This interpretation also frustrates the important federal policy of encouraging the commercialization of federally-supported non-profit entity originated technology as premised in the Bayh-Dole Act and undermines the innovative partnership between government, universities and private industry.

The Federal Circuit is deeply divided on the issue of whether the statute requires a separate written description

beyond that sufficient to enable a skilled artisan to make and use the invention. Yet the court repeatedly refuses to clarify its confusing written description jurisprudence. Since the *Lilly* decision in 1997, the written description issue has percolated through various panels of the Federal Circuit. These divergent opinions cry out for a "better informed and more enduring pronouncement by this Court." *Arizona v. Evans*, 514 U.S. 1, 24 n.1 (1995). The issue is ripe for review and deserves clarification.

UNDER A PROPER CONSTRUCTION OF 35 U.S.C. § 112, P. 1, WRITTEN DESCRIPTION OF THE INVENTION MUST BE SUFFICIENT TO ENABLE

A. Section 112, Paragraph 1 Must Be Interpreted to Effectuate the Patent Bargain

Before this Court is the fundamental question of the proper statutory interpretation of the 35 U.S.C. § 112, P. 1. This question is essential to patent law because the disclosure requirement of § 112, P. 1 embodies the *quid pro quo* of the patent bargain. In return for an enabling disclosure, the patentee receives the right to exclude others from making, using or selling its invention for a limited period of time.[4]

As this Court has recognized, the patent bargain is carefully crafted to balance the benefits between the inventor and the public.

> The applicant . . . who is willing to reveal to the public the substance of his discovery and 'the best

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4. Article I, § 8, clause 8, of the Constitution gives Congress the power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."

> mode . . . of carrying out his invention' . . . is granted 'the right to exclude others from making, using or selling the invention throughout the United States' for a certain period. The federal patent system thus embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design in return for the exclusive right to practice the invention for a period of years. . . .

Bonito Boats, Inc. v. Thunder Craft Boats Inc., 489 U.S. 141, 150-51 (1989). *See J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 142 (2001) ("[T]o obtain a utility patent, a breeder must describe the plant with sufficient specificity to enable others to 'make and use' the invention after the patent term expires. The disclosure required by the Patent Act is "the *quid pro quo* of the right to exclude.").

The benefit to the public derives from the ability to use the invention after the patent expires. Accordingly, the *quid pro quo* of the patent bargain is not achieved unless the public is taught how to make and use the patented invention. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 731 (2002).

> [T]he patent laws require inventors to describe their work in 'full, clear, concise, and exact terms,' 35 U.S.C. § 112, as part of the delicate balance the law attempts to maintain between inventors, who rely on the promise of the law to bring the invention forth, and the public, which should be encouraged to pursue innovations, creations, and new ideas beyond the inventor's exclusive rights.

Id. See also Universal Oil Prods. Co. v. Globe Oil & Refining Co., 322 U.S. 471, 484 (1944) ("The quid pro quo is

disclosure of a process or device in sufficient detail to enable one skilled in the art to practice the invention once the period of monopoly has expired. . . .") The disclosure provision of § 112, P. 1 must be interpreted in a manner that effectuates the patent bargain.

Notably, the patent bargain does not require description for description's sake. If one of skill in the art can understand what the invention is and how to make and use it, the objectives of the patent bargain have been achieved. In the context of university research, the heightened requirement of a precise structural description impedes the prompt transfer of pioneering discoveries to the public. Researchers must divert precious resources to needlessly disclose permutations of the invention already appreciated by the skilled artisan. To require more description than necessary for enablement skews the carefully crafted balance of the patent bargain and frustrates the essential policies of encouraging innovation and competition.

B. The Proper Interpretation Based On The Express Statutory Language Is A Disclosure Sufficient to Enable

A plain reading of the statute confirms that the proper interpretation of § 112, P. 1 is a disclosure of the claimed invention sufficient to enable. Section 112, P. 1 provides:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same. . . .

According to the express statutory language, the written description of the invention must be sufficient to enable the skilled artisan to make and use the claimed invention.

See Festo, 535 U.S. at 731 ("[T]he patent laws require inventors to describe their work in 'full, clear, concise, and exact terms. . . .'") As aptly described by Chief Judge Markey:

> There is no surplusage in saying, as the Congress in effect did, "a written description of the invention
>
> * * * in such full, clear, concise, and exact terms as to enable," and "[a written description] of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable * * *." On the contrary, Congress saved words by specifying, in a single prepositional phrase, that the description of the invention, and the description of the manner of making and using it, shall both be in "such full, clear, concise, and exact terms as to enable." Section 112, first paragraph, is a simple sentence, with a comma after "it," making the phrase "in such full * * * the same" a modifier of both objects of the verb "contain." All before that comma prescribes what shall be described. The phrase following the comma prescribes how and for whom it shall be described.

In re Barker, 559 F.2d 588, 594-95 (CCPA 1977). No other disclosure is statutorily required.

C. The Written Description Requirement Never Was Interpreted As a Free-Standing Patentability Standard Prior to Lilly

The historical and legal context of the disclosure provision demonstrates that no written description of the invention beyond enablement is required by the modern statute. Prior to the introduction of claims, the Patent Statute required that the patent applicant

> deliver a written description of his invention, and of the manner of using, or process of

> compounding, the same, in such full, clear and exact terms, as to distinguish the same from all things before known, and to enable any person skilled in the art or science of which it is a branch, or with which it is most nearly connected, to make, compound and use the same. . . .

Evans v. Eaton, 20 U.S. 356, 430 (1822). This early written description requirement is the "historic predecessor of modern claiming requirements." Mueller, Janice M., *The Evolving Application of the Written Description Requirement to Biotechnological Inventions*, 13 Berkeley Tech. L.J. 615, 620 (1998). After claims were introduced in 1870, the written description no longer served the public notice function and that part of the statute was deleted.

From 1870 to the present, the statute remained virtually unchanged. *See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 27 (1997). ("The 1952 Patent Act is not materially different from the 1870 Act with regard to claiming, reissue, and the role of the PTO.") According to one commentator, The written description requirement became an "historical anachronism without a role in the statutory scheme." Mueller, 13 Berkeley Tech. L.J. at 620.

In 1967, the Court of Customs and Patent Appeals ("CCPA") added a judicial gloss to the disclosure requirement of § 112, P. 1. *In re Ruschig*, 379 F.2d 990 (CCPA 1967). The court employed the judicial fiction of a separate written description rule to policy priority.[5] As Judge Rich, the first

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5. The judicially created written description requirement was used in three circumstances: 1) where an applicant asserts entitlement to an earlier filing date of a previously filed application; 2) in the interference context; and 3) in a case involving a single application, where the claim at issue is added subsequent to filing of the application. *In re Smith and Hubin*, 481 F.2d 910, 914 (CCPA 1973).

judge to use written description in this way, explained: "The function of the description requirement is to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him." *In re Wertheim*, 541 F.2d 257, 262 (CCPA 1976).

In view of the express statutory language of § 112, P. 1, some judges of the CCPA questioned whether the judicially created written description rule was necessary. *See In re Barker*, 559 F.2d at 594 (Markey, C.J., dissenting). As Chief Judge Markey explained:

> The attempt to create historical and current statutory support for a 'separate description' requirement, which was solely a judicial (and unnecessary) response to chemical case in which appellants were arguing that those skilled in the art 'might' make and use a claimed invention is mistaken.
>
> * * *
>
> [I]t would have been better if the court had held, in certain past chemical cases, that whatever 'enablement' was present, it was not in 'full, clear concise and exact terms,' rather than to have created a 'separate description' gloss."

Id. at 594-95.

Early Federal Circuit precedent reflected both views of the disclosure requirement of § 112, P. 1.[6] In 1991, the Federal

6. Compare *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575 (Fed. Cir. 1985), *quoting In re Kaslow*, 707 F.2d 1366, (Cont'd)

Circuit reaffirmed the separate written description requirement for policing priority found in the *Ruschig* line of cases. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555 (Fed. Cir. 1991). The court acknowledged that the separate requirement was a judicial creation and not a matter of statutory interpretation. *Id.* at 1561. *Vas-Cath* remained the leading case in written description precedent until the Federal Circuit's decision in *Regents of the University Of California v. Eli Lilly and Co.*, 119 F.3d 1559 (Fed. Cir. 1997).

UNIVERSITY RESEARCH FLOURISHED BASED ON A WRITTEN DESCRIPTION SUFFICIENT TO ENABLE

In the 1980's, the expansion of patentable subject matter and new federal patent policy stimulated fundamental research at academic institutions. These changes significantly impacted the biotechnology industry and spurred the development of intellectual property rights. First, this Court opened the legal floodgates to patenting of biotechnology research when it expanded the scope of patentable subject matter to include living organisms. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

Second, Congress enacted the Bayh-Dole Act. Bayh-Dole was designed to use the patent system to encourage the transfer of technology generated by government-supported research to the public for its benefit and welfare. 35 U.S.C. § 200 ("It is the

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(Cont'd)
1375 (Fed. Cir [illegible]he test for sufficiency of support in a parent application is whether the disclosure of the application relied upon 'reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter.'"), with *Kennecott Corp. v. Kyocera Int'l, Inc.*, 835 F.2d 1419, 1421 (Fed. Cir. 1987), *cert. denied*, 486 U.S. 1008 (1988) ("The purpose of the description requirement of [§ 112, P. 1] is to state what is needed to fulfill the enablement criteria. These requirements may be viewed separately, but they are intertwined.").

policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development. . . ."). The highly productive university-industry relationships fostered by Bayh-Dole yielded new biomedical products and spawned a robust U.S. biotechnology industry. *See* Locke, Scott D., *Patent Litigation Over Federally Funded Inventions and the Consequences of Failing to Comply with Bayh-Dole*, 8 Va. J.L. & Tech. 3 (2003).

The Bayh-Dole Act created a federal uniform patent policy that "revitalize[d] the American economy and scientific community by removing the obstacles that the federal government had developed previously against technology transfer. . . ." Dueker, Kenneth Sutherlin, *Biobusiness on Campus: Commercialization of University-Developed Biomedical Technologies*, 52 Food Drug L.J. 453 (1997). Central to Bayh-Dole was the role of patents in facilitating technology transfer between university labs and private industry. *See* Eisenberg, Rebecca S., *Symposium on Regulating Medical Innovation: Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 Va. L. Rev. 1663, 1698-99 (1996). Universities needed to attract commercial licensees to invest in development because they were not equipped to develop new discoveries into commercial products. Vesting patent ownership in universities facilitated this process by providing a source of exclusive rights that would supply the incentive for the private sector to engage in such development efforts.

Bayh-Dole became the foundation of university technology transfer.[7] 52 Food & Drug L. J. at 508. Prior to

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7. *The Economist* classified the Bayh-Dole Act as "Possibly the most inspired piece of legislation to be enacted in America over the past half-century . . ." and further referred to it as "Innovation's Golden Goose." *The Economist*, 2002 WL 7248586 (December 14, 2002).

Bayh-Dole, fewer than 250 patents were issued to universities annually, and many valuable research ideas never reached the marketplace. *Id.* Ten years later, that number had risen to over 1600 patents per year, 80% of which resulted from federally funded research. *Id.* By 1996, university licensing activity was having a major economic impact, adding more than 24.8 billion dollars and 212,500 jobs to the national economy each year. Hamilton, Clovia, *University Technology Transfer and Economic Development Proposed Cooperative Development Agreements Under the Bayh-Dole Act*, 36 Marshall L. Rev. 397, 408 (2003). Against the backdrop of this highly successful implementation of federal patent policy, the drastic change in written description law occurred.

THE NEW WRITTEN DESCRIPTION DOCTRINE UPSETS THE SETTLED EXPECTATIONS OF RESEARCH INSTITUTIONS

In 1997, the Federal Circuit for the first time applied the judicially created written description requirement as a general disclosure requirement in place of the statutorily mandated enablement standard. *Lilly*, 119 F.3d at 1566-1567. Borrowing heavily from prior precedent concerning biotechnology inventions,[8] the court imposed a *per se* written description test, under which the inventor must demonstrate that its biotechnology invention has been reduced to practice and described in structural detail.

Lilly sent a shock wave through public and private research institutions. Before *Lilly*, adequate written description of chemical and biotechnological compounds had been satisfied by descriptions in terms of function, properties, methods of making, or any other manner sufficient to convey possession of the invention. Mueller, 13 Berkeley Tech. L.J.

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8. *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200 (Fed. Cir. 1991); *Fiers v. Revel*, 984 F.2d 1164 (Fed. Cir. 1993).

at 624. By requiring a precise structural description, *Lilly* "obscure[d] the function and purpose of the written description requirement by unnecessarily restricting the manner in which possession of a biotechnological invention can be conveyed." *Id.* at 633. Moreover, *Lilly* instituted a *per se* rule of written description that eliminated the perspective of one of skill in the art and required far more disclosure than necessary to satisfy the enablement requirement. Instead of focusing on the next ground-breaking discovery, *Lilly* required that university researchers describe every variant of their last invention in excruciating detail.

Following *Lilly*, the Federal Circuit in *Rochester* manufactured a separate statutory basis for its new free-standing written description requirement. By parsing the statute such that the enablement clause modifies only the second part of the written description, the panel concluded that three separate requirements are contained in the statutory provision: (1) a written description of the invention; (2) a written description of the manner and process of using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same; and (3) the best mode. *University of Rochester v. G.D. Searle*, 358 F.3d 916, 921, *reh'g denied* 375 F.3d 1303. Relying on its new statutory interpretation, the Federal Circuit in *Rochester* vastly expanded the reach of the new written description rule to all technologies.

These drastic changes in the disclosure requirement of § 112, P. 1 dramatically upset the settled expectations of the inventing community. Not only does the new written description doctrine impact the patenting of new inventions, it also threatens the validity of already-issued patents. Further, the new written description doctrine undermines the policies of Bayh-Dole, and frustrates prompt disclosure of new inventions to the public.

A. The New Written Description Requirement Frustrates Prompt Disclosure of New Inventions To The Public

The new, free-standing written description requirement frustrates the Constitutional objective of early disclosure of inventions to the public because of the added costs and burdens associated with preparing a sufficiently detailed specification.[9] Not only are inventors required to actually reduce their inventions to practice, but they also must provide a precise detailed description. In *Moba B.V. v. Diamond Automation*, Judge Rader illustrated this problem for biotechnology inventions:

> Even if a drafter of biotechnological patents now knows the new law, compliance may tax a drafter beyond reasonable limits. . . . [A] "precise definition" of the new protein, as required by *Lilly*, apparently requires tedious disclosure of thousands of potential permutations of the amino acid sequence that all fall within a proper description of the protein's functions, properties, and DNA source.

325 F.3d 1306, 1325 (Fed. Cir. 2003) (Rader, J. concurring) (footnote omitted).

The extra work may take months of researcher time, consume precious research dollars that could be used to fund other projects and delay disclosure of the fundamental invention and thus its exploitation by others. Without the speedy disclosure of biotechnology inventions, the public

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9. *See* Jeffie A. Kopczynski, *A New Era for §112? Exploring Recent Developments in the Written Description Requirement as Applied to Biotechnology Inventions*, 16 HARV. J.L. & TECH. 229, 253 (Fall 2002).

may "very well be deprived of life-saving technology, such as pharmaceutical drugs to treat a life-threatening medical disease." Kelly, David, *The Federal Circuit Transforms the Written Description Requirement into a Biotech-Specific Hurdle to Obtaining Patent Prosecution for Biotechnology Patents*, 13 ALB. L.J. SCI. & TECH. 249-250 (2002).

The new written description requirement also significantly increases the risk for venture capitalists and other investors, particularly investors in biotechnology companies. It almost certainly will reduce future funding for, and investment in, biotechnology research. Kopczynski, 16 HARV. J.L. & TECH. at 252-53. If inventors are less likely to be able to fully realize the financial benefits of their research through valid and enforceable patents, then private investors and public funds are much less likely to see a return on their investment dollars. *Id.*

B. Under the New Written Description Requirement, Issued Patents Risk Invalidity

The new written description doctrine has become a powerful weapon in the arsenal of accused infringers and places a cloud of uncertainty on the validity of already issued patents. Prior to 1997, inventors provided a disclosure that was sufficient to enable those skilled in the relevant art to make and use the claimed invention. The *Rochester* decision, however, measures each and every patent application against its precise structural written description standard. "Under this new disclosure test, every case where the written description does not specifically disclose some feature of the claimed invention will give rise to a validity challenge." *Rochester*, 375 F.3d at 1314 (Rader, J., dissenting).

This Court repeatedly has cautioned against adopting such sweeping changes to patent law. *Festo*, 535 U.S. at 739,

citing Warner-Jenkinson, 520 U.S. at 28. ("[F]undamental alterations in [patent] rules risk destroying the legitimate expectations of inventors in their property.") "To change so substantially the rules of the game now could very well subvert the various balances the PTO sought to strike when issuing the numerous patents which have not yet expired and which would be affected by our decision." *Id*, *citing Warner-Jenkinson* at 32 n.6. Especially in the university sector, a written description requirement severed from enablement can have severe consequences, depriving the public of fruits of federally-supported basic research.

C. The New Written Description Doctrine Interferes with the Policy of Bayh-Dole

The new, free-standing written description doctrine frustrates the policy objectives of Bayh-Dole. The increased burden on university researchers to describe their inventions (far beyond that required for enablement) has a chilling effect on the innovative and economic success realized under the Bayh-Dole Act. The heightened written description bar taxes the resources of many university and non-profit entities "beyond reasonable limits," *Moba*, 325 F.3d at 1325 (Rader, J. concurring), by forcing them to perform further development activities more appropriately allocated to the private sector. Rather than straining to respond to a written description requirement, the preparation for which may be costly and time consuming, research institutions instead may be forced to surrender their valuable patent rights. The heightened written description requirement thus resurrects the barriers to innovation and competition that Bayh-Dole removed.

THE DEEP CONFLICT IN THE FEDERAL CIRCUIT OVER WRITTEN DESCRIPTION MUST BE RESOLVED BY THIS COURT

The *Amici* strongly urge the Court to grant the University of Rochester's Petition in this case. Although cognizant of the deleterious effect of the new written description requirement on the biotechnology industry, the deeply divided Federal Circuit refuses to resolve this conflict. Since the *Lilly* case was decided in 1997, the issue of written description has percolated in the Federal Circuit. *See Rochester*, 375 F.3d at 1327 (Linn, J., dissenting from denial of rehearing *en banc*) ("*Lilly* changed the landscape and set in motion the debate the panel opinion in this case perpetuates.") As Judge Newman explained, "The issue of whether patent law contains a separate written description requirement has percolated through various panels of the [Federal Circuit] on a variety of facts." *Id.* at 1305 (Newman, J., dissenting). This percolation has yielded a great number of divergent opinions by the judges of the Federal Circuit.[10]

The Federal Circuit routinely issues split decisions in biotechnology patent cases that raise written description. For example, in *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 323 F.3d 956 (Fed. Cir. 2002), the court strictly applied the *Lilly* rule and invalidated the patent for lack of written description. This opinion created "an immediate firestorm." *See Rochester*, 375 F.3d at 1308 (Rader, J., dissenting from denial of rehearing *en banc*). Within a few months, the Federal Circuit vacated its original opinion and issued a second opinion that reversed the result. *Id.*

10. *See Moba B.V. v. Diamond Automation*, 325 F.3d 1306 (Fed. Cir. 2003). In *Moba*, Judge Rader urged the overruling of the *Lilly* decision. *Id.* at 1326. Judge Bryson, who sat on the *Lilly* panel, indicated that rather than overrule *Lilly*, the proper result might be to overrule the entire *Ruschig* line of cases to eliminate entirely a separate written description requirement. *Id.* at 1328.

The Federal Circuit denied the subsequent petition for rehearing *en banc*, accompanied by four separate opinions. Two judges expressed the view that written description is preeminent: the *quid pro quo* of the patent system. *Enzo*, 323 F.3d at 971. In contrast, at least three other judges viewed written description as subsumed in the enablement inquiry. *Id.* at 981. Judge Rader stated that *Lilly* and *Enzo* apply a "new, free-standing disclosure requirement" that requires more specific disclosure than enablement, and "threatens to further disrupt the patent system by replacing enablement." *Id.* at 982. Judge Linn opined that the measure of sufficiency of the written description doctrine "should depend solely on whether it enables a person skilled in the art . . . to make and use the claimed invention." *Id.* at 988.

In *Amgen v. Hoechst Marion Roussel*, 314 F.3d 1313 (Fed. Cir. 2003), a different panel limited the *Lilly* rule to new or unknown biological material. *Id.* at 1332. Judge Clevenger dissented, stating that the district court's approach was not "faithful to this court's articulation of the written description requirements of section 112 as expressed in *Lilly*." *Id.*

In *Rochester*, the Federal Circuit fractured over written description. Five separate opinions accompanied the order denying rehearing *en banc*, with each judge advocating a different interpretation of the statute.

Two judges concurred. Judge Lourie argued for a separate written description requirement mandated by statute: "Contrary to the assertions of the appellant, certain amici, and some of the dissenters, there is and always has been a separate written description requirement in the patent law." *Rochester*, 375 F.3d at 1305. Although Judge Dyk also concurred, he commented that his concurrence "should not be taken as an endorsement of our existing written description jurisprudence." *Id.* at 1307.

Judge Newman, although professing agreement with Judge Lourie's view, dissented: "This question has been promoted from simple semantics into a fundamental conflict concerning patent scope and the support needed to claim biological products. The appropriate forum is now the *en banc* tribunal, not continuing debate in panel opinions applying divergent law." *Id.* at 1304.

Judge Linn also dissented, opining that "the measure of the sufficiency of written description" depends on whether it enables a skilled artisan to make and use the claimed invention. *Id.* at 1325. He further explained:

> The question presented by 35 U.S.C. § 112, paragraph 1, is not, 'Does the written description disclose what the invention is?' The question is, 'Does the written description describe the invention recited in the claims—themselves part of the specification—in terms that are sufficient to enable one of skill in the art to make and use the claimed invention and practice the best mode contemplated by the inventor?' That is the mandate of the statute and is all our precedent demanded prior to Regents of the University of California v. Eli Lilly & Co. . . .

Id.

Finally, Judge Rader dissented, stating that there was no legal basis for the new, free-standing written description requirement. Under both a plain reading of the statute and legal precedent, "enablement [is] the only substantive test . . . in the first paragraph of § 112." *Id.* at 1308 n.3. Judge Rader also pointed out that the new requirement "changes the established rules of claiming and disclosing inventions" and creates consequences not considered by the court or intended by Congress. *Id.* at 1313.

The Federal Circuit is deeply divided over the statutory interpretation of § 112, P. 1. If left unresolved by this Court, contradictory, panel-specific decisions concerning patentability and invalidity will continue to issue. Such continued uncertainty does great harm to the patent system and in particular, the biotechnology industry.

CONCLUSION

The continued application of the new written description requirement threatens to destroy the partnership among government, industry and universities that has fueled the biotechnology industry and produced many life-saving biomedical products. The issue of written description is a "frontier legal problem that deserves resolution." *See Arizona v. Evans*, 514 U.S. 1, 24 n.1 (1995). This Court can provide an "informed and enduring final pronouncement" on this issue. *Id.*

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